VI.2. ELEMENTS FOR A PUBLIC SUMMARY

VI.2.1. Overview of disease epidemiology

Seasonal allergic rhinitis ("hay fever") is due to allergens such as pollen of any plants occurring during the pollinic seasons resulting in sneezing, itching, runny or blocked nose. It is estimated that it affects 10% to 20% of the general population of industrialized countries and 40% of children.

Chronic idiopathic urticaria ("hives") has no known cause leading to wheals, itching. It is estimated to affect up to 1% of the general population of industrialized societies and is more common in adults than in children, with the disease typically beginning in the third to fifth decades of life. Women are affected twice as often as men.

VI.2.2 Summary of treatment benefits

Fexofenadine is used since 1996 for the treatment of symptoms of seasonal allergic rhinitis ("hay fever") and of chronic idiopathic urticaria ("hives") in adults and in children.
Studies have been conducted to measure the antiallergic effect of the drug. They have demonstrated that the medicine exhibits its effect within one hour, achieving maximum at 6 hours and lasting 24 hours. Maximum efficacy was greater than 80%. Clinical studies conducted in seasonal allergic rhinitis have shown that a dose of 120 mg is sufficient for 24 hour efficacy.

VI.2.3. Unknowns relating to treatment benefits

Fexofenadine has been on the market for over 15 years and there is no indication of impaired efficacy or benefits of the treatment.

VI.2.4. Summary of safety concerns

Table 3 - Important identified risks

Risk	What is known	Preventability
Systemic hypersensitivity reactions	Hypersensitivity reactions such as serious allergic reactions which causes swelling of the face or throat (angioedema) or difficulty in breathing or dizziness (systemic anaphylaxis), chest tightness, shortness of breath (dyspnea), flushing are known reactions observed with fexofenadine. The frequency of such events is unknown (cannot be estimated from the available postmarketing data).	Yes, by avoiding the use of fexofenadine in patients who are known to be allergic to fexofenadine or any of the excipients

Table 4 - Important potential risks

Risk	What is known	Preventability
Cardiovascular events (tachycardia and palpitations)[a]	Tachycardia and palpitations are reactions observed with fexofenadine. The frequency of such events is unknown (cannot be estimated from the available postmarketing data).	Yes, by informing healthcare professionals and patients

a Except in MRP countries where this risk is considered as important identified risk on regulatory grounds from health authorities.
MRP: Mutual Recognition Procedure

Table 5 - Missing information

Risk	What is known
Pregnant and lactating women	Studies performed in mice did not affect fertility, did not cause malformation of embryon or foetus (1)(2). However, there are no adequate studies of fexofenadine in pregnancy in human use and that there are no data on lactating women. Therefore, The use of fexofenadine is not recommended during pregnancy unless necessary and breast-feeding.
Treatment of seasonal allergic rhinitis (hay fever) in children aged less than 6 years old	The efficacy and safety of fexofenadine have not been established in children aged less than 6 years old.
Treatment of chronic idiopathic urticaria (hives) in children aged less than 12 years old.	The efficacy and safety of fexofenadine have not been established in children aged less than 12 years old.

VI.2.5. Summary of additional risk minimization measures by safety concern

Not applicable since no additional risk minimization measures are required.

VI.2.6. Planned post authorization development plan

There is no post authorization development plan for fexofenadine.

VI.2.7. Summary of changes to the RMP over time

Table 6 - Summary of changes to the RMP over time

Version	Date	Safety concerns	Comment
1.1	04-Jul-2013	Cardiovascular events (ie, tachycardia and palpitations)	-
1.2	18-Sep-2015	Hypersensitivity reaction	Rephrased to systemic hypersensitivity reactions
		Cardiovascular events (ie, tachycardia and palpitations)	Clarification provided
		Important missing information	Rephrased to missing information

RMP: Risk Management Plan